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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,158	11/21/2000	Russell A. Houser	441742000411	6811
24353	7590	12/04/2003		
BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025			EXAMINER BUI, VY Q	
			ART UNIT 3731	PAPER NUMBER
			DATE MAILED: 12/04/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,158

Applicant(s)

HOUSER ET AL.

Examiner

Vy Q. Bui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Fig. 27 for a plunger, Fig. 40f for a self-expanding fitting and Fig. 10 for an everting tool in Paper No. 11 is acknowledged. However, there is no drawing to illustrate a system of a combination of a self-expanding fitting such as the one shown in Fig. 40f and an everting tool as shown in Fig. 10. In addition, an everting tool is clearly a separate tool by itself and has its own application, therefore, it should be considered as a distinct invention from the system of a combination of a self-expanding fitting as shown in Fig. 40f and a plunger as shown in Fig. 27. The examination is based on Fig. 19a-d with plunger 186 as shown in Fig. 27 and fitting 48 as a self-expanding fitting shown in Fig. 40f.

Claims 23 and 25 related to an everting tool are therefore are restricted and withdrawn from further consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1-3, 7, 10-12, 16, 19-22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by BACHINSKI et al. (6,036,702).

As to claims 1-3, 7, 10-12, 16, 19-22 and 24, BACHINSKI (Fig. 7-9, 34a) discloses tissue tapered tip of component 412 as a tissue dilator and tubular portion of component 412 as a plunger/insertor, tissue puncturing tool 150, flexible sheath 440, nitinol frame 432 and nitinol connector 449 (col. 11, lines 21-37) as a fitting defining a tubular portion and self-expanding petals 436 affixing to silicone cover/by-pass graft 434 (col. 8, lines 4-16) as recited in the claims. Notice that the puncturing tool in the claim does not have any structural limitation to clearly define the tool, therefore, wire 159 can be reasonable considered as a puncturing tool.

2. Claims 4-5 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over BACHINSKI et al. (6,036,702).

As to claims 4-5, 13-14 and 26-27, BACHINSKI discloses collapsible plunger 412 and flexible sheath 440, which plunger 412 and sheath 440 are made of soft materials, inherently, plunger 412 and sheath 440 are longitudinally splittable. Alternatively, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to make sheath 440 and plunger 412 splittable as this configuration are well known in the art to make withdrawing the sheath or the plunger out of a patient body easily and quickly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 8-9, 17-18 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over BACHINSKI et al. (6,036,702).

BACHINSKI discloses substantially all limitations as recited in the claim, except for a needle for puncturing a vessel. It is well known in the art to have a needle to puncture a blood vessel wall to make an opening so as one can drive a guide wire into the opening and into the lumen of the blood vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a needle for puncturing and make an opening for the guidewire 150 to go into a lumen of a blood vessel as this configuration is well known in the art.

2. Claims 4-6, 13-15 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over BACHINSKI et al. (6,036,702) as applied to claims 1, 10 and 19 above, and further in view of EVANS et al. (5,250,033).

BACHINSKI discloses substantially all limitations as recited in the claim, except for the sheath and the plunger are splittable and a hemostatic valve at the proximal side

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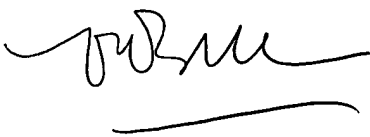
of the device. However, EVANS (Figs. 1-2) shows splitable sheath 12 for easy removal of the sheath and valve 20 for hemostatic valve or seal for sealing a gas/fluid/blood in the body of a patient from the outside environment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a splitable sheath/plunger and a valve so as to facilitate the removal of the sheath/plunger and to seal a gas/fluid/blood in the body of a patient from the outside environment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB
11/30/2003